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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/801,985	03/16/2004	Carlin Long	MYOG:034US	3059

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EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 03/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

HL

Office Action Summary	Application No.	Applicant(s)	
	10/801,985	LONG ET AL.	
	Examiner	Art Unit	
	Raymond J. Henley III	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *1-10* is/are allowed.

6)☒ Claim(s) *11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)

2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3)☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4)☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.

5)☐ Notice of Informal Patent Application (PTO-152)

6)☐ Other: _____.

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

Applicants' Terminal Disclaimer and amendment filed January 12, 2005 has been received and entered into the application. Accordingly, the specification at page 2, lines 2-6 has been amended.

In view of the acceptable nature of the Terminal Disclaimer, the rejection of claims 1-15 under the judicially-created doctrine of obviousness double patenting, as set forth in the previous Office action dated October 8, 2004, is withdrawn.

Specification

Applicants' amendment to page 2, lines 2-6 of the present specification is noted. Such amendment is objected to because each relationship of continuing application 10/256,221 has not been pointed out.

Applicants should amend the specification so that the relationship between the various priority documents are clearly set forth, (as well as to indicated the current status of the '221 application), e.g., "This application is a continuation of U.S. Serial No. 10/256,221, now U.S. Patent No. 6,706,686, which claims benefit of priority to U.S. Provisional Serial Nos. ...".

Allowable Subject Matter

Claims 1-10 are deemed allowable.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating heart failure, does not reasonably provide enablement for preventing such failure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The burden of enabling the prevention of heart failure would be much greater than that of enabling the treatment thereof. In the instant case, the specification does not provide guidance as to how one skilled in the art would accomplish the objective of preventing heart failure or how a patient could be kept from every being susceptible to this conditions. Nor is there any guidance provided as to a specific protocol to be utilized in order to show the efficacy of the presently claimed active ingredients for preventing heart failure.

Specifically, it is highly unlikely, and the Office would require experimental evidence to support the contention that the claim specified active could actually prevent heart failure and other edematous conditions by simply administering, by any method, an amount of the claim specified active agents. The specification fails to enable one of ordinary skill in the art to practice the claimed methods for preventing heart failure.

The term "prevention" or "preventing" may be reasonably interpreted as being synonymous with the term "curing" (see MPEP § 2111) and both circumscribe methods of treatment having absolute success. Since absolute success is not reasonably possible with most diseases/disorders, especially those having etiologies and pathophysiological manifestations as complex/poorly understood as heart failure, (note the present specification at page 2, line 16 – page 3, line 22), the specification, which lacks a showing that heart failure could actually be

prevented, is viewed as lacking an adequate enabling disclosure of the same.

The present specification is evaluated by the Examiner as directed by the Court in *In re Marzocchi et al.* , 169 USPQ 367 (CCPA 1971):

"Specification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that heart failure could be actually prevented is doubted because the term "prevention" or "preventing" is synonymous with the term "curing" and both circumscribe methods of treatment having absolute success and because absolute success is not reasonably possible with most diseases/disorders.

Also, as disclosed by Applicants at page 8, lines 24-28, "Heart failure is one of the leading causes of morbidity and mortality in the world. In the U.S. alone, estimates indicate that 3 million people are currently living with cardiomyopathy and another 400,000 are diagnosed on a yearly basis. Dilated cardiomyopathy (DCM), also referred to as "congestive cardiomyopathy" is the most common form of the cardiomyopathies and has an estimated prevalence of nearly 40 per 100,000 individuals (Dumnd et al., 1995).". Such would appear indicative that the art is currently unaware of any therapeutic regimen that is effective for the prevention of heart failure and that by merely disclosing that a particular agent or class of agents could prevent heart failure, Applicants would not imbue the skilled artisan with a reasonable expectation that such would actually be the case.

The Examiner further doubts that heart failure may be kept from ever occurring because

Cecil (cited by the Examiner as reference "U" on the attached form PTO-892), states "Heart failure may be prevented by decreasing the risk of the initial cardiac injury or, if the injury has already occurred, by decreasing the early and continuing loss of myocardium. Specific interventions can alter the development and progression of heart failure during each phase of the disease (Fig. 48-3). (page 217, col. 1, under the heading "Prevention of Heart Failure"). This disclosure would appear to only indicate that the term "prevented" is used in the context of inhibited or else the incidence could be reduced because the authors only speak of reducing the risk of the underlying causes for heart failure and not the total elimination thereof. Some degree or incidence of heart failure would be reasonably expected.

Accordingly, the claims are deemed properly rejected.

Insofar as this rejection represents a new ground of rejection, the present Office action is not made final.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Raymond J Henley III
Primary Examiner
Art Unit 1614

March 14, 2005